This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.

Bayer

Agriculture Division

Crop Protection Products

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Via Federal Express

October 1, 1999

Ms. Kylie Rothwell
Special Review and Reregistration Division (H7508W)
U.S. Environmental Protection Agency
401 M Street, NW
Washington, D.C. 20406

Subject: **Trichlorfon, Case # 0104**
Health Effects Division Preliminary Human Health Risk Assessment

Dear Ms. Rothwell:

Bayer Corporation is responding to your request for comments on errors, confidential business information and to indicate data Bayer intends to submit to the Agency in support of the active ingredient **trichlorfon**. We would like to point out the following errors that we feel are in the scope of error correction as defined in your letter. The general acute toxicity categories reported in the hazard identification section of the document appear to be incorrect. The following statement is made: "In general, based on animal studies, trichlorfon is acutely toxic via the oral and dermal routes of exposure (Category II), has low inhalation toxicity (Category III), causes slight eye irritation (Category III), and is a moderate skin sensitizer. It causes mild skin irritation." This information is inconsistant with the currently accepted studies referenced in the RED as well as with new data that have been provided. The following studies were referenced in the RED:

Gdln #	Test	MRID #	Category
81-1	Oral LD_{50}	00256446	II
81-2	Dermal LD_{50}	00090786	III
81-3	Inhalation LC_{50}	00256446	IV
81-4	Eye Effects	41571302	III
81-5	Skin Effects	40306901	IV
81-6	Skin Sensitization	00257599	Sensitizer

The following studies were submitted in January and February of 1998 and show the following toxicity categories:

Gdln #	Test	MRID #	Category
81-2	Dermal LD_{50}	44479407	III
81-2	Dermal LD_{50}	44479410	III
81-4	Eye Effects	44471301	II

We also feel obliged to point out the fact that the risk assesment described above utilized only a screening assessment for occupational and residential exposure. The screening evaluations for residential exposure are based on extremely conservative default assumptions and are intended to identify ***potential*** risks. The Agency has stated its current position regarding the use of these models as "Risks are considered to be of no concern if model estimates show insignificant risks. Risks are considered to be of potential concern if model estimates show significant risks." The Agency has also stated that the use of these models may greatly overestimate the actual exposure. We know this is the case for trichlorfon based on actual exposure and residue data. EPA's current risk evaluation of trichlorfon is a very preliminary, extremely conservative assessment based on default assumptions (generally unrealistic) and little or no actual data. Trichlorfon has a long and safe use history in the residential and commercial turf market. The safety of trichlorfon, was extensively evaluated by Bayer and the EPA prior to its initial registration in 1956 and on a continuing basis since then. Bayer is not aware of, nor has the EPA indicated the existence of, any evidence that would bring into question the safety of trichlorfon under current actual use conditions. The risks estimated by EPA are in no way reflective of those associated with actual use and do not take advantage of available data. Based on existing exposure data and trichlorfon use information, Bayer plans to submit to EPA a refined risk assessment for trichlorfon using data from the Outdoor Residential Exposure Task Force by the end of the year.

We feel it is also important to point out the following concerns in regard to the drinking water assessment:

1. Bayer notes that the drinking water exposure assessment was based on Tier I (GENEEC) predictions for turfgrass. It is widely recognized that predictions using GENEEC are not sufficiently refined to be meaningful in a risk assessment. The OPP stated previously that exposure results obtained from modeling using a stagnent farm pond as a potential drinking water source should not be used in human health risk assessments:

   „OPP wishes to emphasize that the GENEEC and PRZM/EXAMS modeling of an edge of field farm pond is not appropriate for generating accurate estimates of pesticides or degradates in actual drinking water, and **should not be used directly in computing aggregate exposures for purposes of estimating human risks.**" Reference: OPP's Interim Apporoach for Addressing Drinkging Water Exposure. Memorandum from Stephen Johnson to OPP Division Directors, November 17, 1997.

   Therefore, the Agency should not use the results reported in the HED preliminary risk assessment. The proper implementation of EPA policy in this case is particularly important because the risk assessment, as proposed, suggests that drinking water is a primary contributor of risk to humans. An improper application of the drinking water exposure assement in this case will have significant implication with respect to the extent of exposure/risk mitigation that is required to resolve the FQPA concern.

2. While EPA policy excludes the use of GENEEC modeling in the human health risk assessment, it is still appropriate to indicate an error associated with using the Tier I methodology for turf applications. The OPP is correct in stating that no refined screening models are available for turfgrasses, so EFED reported the simplified (Tier I) exposure value. Bayer recognizes that the GENEEC model is a "metamodel"

developed with a cotton production scenario for Mississippi. In effect, GENEEC is based on the results of Tier II (PRZM/EXAMS) modeling of cotton grown on the loring silt loam soil. The hydrology and chemical runoff (fixed at 10% of the residual mass following the last application) are „reasonable worst case" estimates for cotton, but may be highly overpredictive for turfgrass. Recognizing that OPP acknowledges the inability to predict runoff losses from turf using PRZM/EXAMS, Bayer suggests that it is equally inappropriate, and in fact incorrect, to make exposure predictions for turfgrasses using a simplified metamodel (i.e. GENEEC) derived from the Tier II models previously identified as being inappropriate. In summary it is incorrect to use GENEEC to estimate runoff and subsequent drinking water exposure from turfgrasses.

3. The most recent Reregistration Eligibility Document (RED) for tricholorfon, issued in January, 1997 (EPA 738-R-96-017) indicates that EFED prepared an exposure assessment for turf using PRZM version 1.0 and EXAMS version 2.94 (refer to RED, page 34). It appears that OPP has since recognized the limitations of this exercise for turfgrasses and therefore did not bring the exposure results into the current human health risk assessment. In any case, Bayer would appreciate an opportunity to review the details of this exposure assessment in the form of the EFED/EFGWB modelling summary referenced on page 36 of the RED. Further, Bayer would appreciate an opportunity to review the details of the GENEEC analyses performed in support of the HED risk assessment. The detals of these exposure predicitions are not provided in the preliminary assessment document. This is important because the exposure results used in the risk assessment seem inconsistent with the environmental data summarized in the RED. For example, the RED details a hydrolysis report (MRID 00148974) in which half-lives at pH 5, 7 and 9 were 104 days, 34 hours and 31 minutes, respectively. An aerobic aquatic study (MRID 40338602) provided a half-life in pond water of 8 hours at pH 8 with relative stability shown at pH 5. Aerobic soil metabolism studies (MRID 00098625 abd 42243701) resulted in half-lives ranging from 4.5 to 10 days. The half-life in anaerobic soil the half-life is only 1.8 days (MRID 42243701). In summary, the data demonstrate that trichlorfon is short- lived in soil and aquatic systems whereby it is highly unlikely that chronic exposures on the order of 151 ppb would be expected over a period of 56 days following a single runoff event.

Please contact Mr. Charles Boyd of my staff at (816) 242-2457 for any further information.

Sincerely,

John A Thornton

John S. Thornton
Director
Product Registrations and Regulatory Affairs